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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,544	09/10/2003	Hidenobu Senpuku	242617US0	3249

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/20/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/658,544	SENPUKU ET AL.	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 18 January 2007 is acknowledged and has been entered. Claims 2-8 are newly added. Claim 1 has been cancelled. Claims 2-8 remain in the case.

The disclosure remains objected to because of the following informalities: the specification is replete with grammatical, idiomatic, and spelling errors too numerous to be specifically listed and should be carefully revised. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification is objected to and claims 2-8 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record, in the prior rejection of the similar subject matter of claim 1, that the specification contains subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth, applicant teaches that determining the quantity of *Streptococcus mutans* in human saliva does not correlate with caries risk for a number of reasons (see e.g. pages 2-3). Moreover, the art would also suggest that any relationship between dental caries, saliva levels of cariogenic organisms, and immune responsiveness would be unpredictable because of the many other factors, such as tooth anatomy, diet, and health, which influence caries formation (see, e.g., Acton et al., Hum. Immunol. 60: 984, 1999, page 988). Yet, determining the quantity of *Streptococcus mutans* in human saliva at a single time point is the only measure put forth in the instant specification for correlating the level of IgA antibodies to caries risk. Moreover, the levels of *Streptococcus mutans* detected in human saliva by applicant (e.g. Table 1, page 20) would be considered high by others skilled in the art (see, e.g., Acton et al., Hum. Immunol. 60: 984, 1999, Tables 1 and 2, page 987), irrespective of whether the patients demonstrated high or low levels of IgA antibody. Therefore, as set forth, any correlative relationship between IgA antibodies at a single time point and caries risk is purely speculative and unpredictable according to applicant's own teachings (and those of the prior art), one would question applicant's possession of the invention as disclosed and/or claimed and one would not be assured of the ability to practice the invention as disclosed and/or claimed absent further written description and guidance from applicant.

Applicant's arguments filed 18 January 2007 have been fully considered but they are not deemed to be persuasive. Applicant urges that the specification exemplifies that determination of a single level of antibodies correlates with caries risk because of a correlation of antibody level, initial adhesion of mutans streptococci to the tooth surface, and therefore the level of *S. mutans*. This is not found persuasive for the reasons of record. Notwithstanding applicant's

arguments to the contrary, there are no teachings correlating antibody level with anything other than a single determination of the level of *S. mutans* in human saliva, a measure that applicant and the prior art teach does not correlate with caries risk for a number of reasons. There is no teaching or showing regarding the level of bacterial adhesion to teeth in the presence of the various antibody levels in the patients, all of which were harboring various levels of *S. mutans* in their saliva, as asserted. Moreover there is nothing to support any correlation between lower tooth adhesion and lower saliva bacterial levels as asserted by applicant. Patients with higher salivary levels of bacteria may just as likely have these higher levels at the particular assay point because less of the bacteria are adhering to teeth.

Claims 2-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant describes and teaches the peptide consisting of SEQ ID NO: 2 (see, e.g., pages 8 and 11) as the relevant antigen for determination of patient saliva immunoglobulin A specific therefor. The peptide consisting of SEQ ID NO: 1 is taught as a MHC class II molecule-binding epitope (see pages 7-8), not as one for detection of antibody binding. Absent further written description and guidance from applicant, one would question applicant's possession of the invention as now claimed and one would not be assured of the ability to practice the invention as

now claimed. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to these claims, the specification, as originally filed, does not provide support for the secretory immunoglobulin A (IgA) being labeled. Applicant teaches labeled anti-human immunoglobulin A antibodies in the method for detection of human IgA. Although one of skill in the art might realize from reading the disclosure that labeled sample immunoglobulins are useable in the invention, such possibility of use does not provide explicit or implicit indication to one of skill in the art that such were originally contemplated as part of applicant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Note that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "low" and "high" in claim 2 are relative terms which render the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Matsushita et al. (Inf. Imm. 62: 4034, 1994) in light of the instant disclosure for reasons similar to those of record in the prior rejection of the similar subject matter of claim 1. As set forth, the reference determined linear epitopes in the A-region of PAc which bound the salivary IgA antibodies (see Fig. 4). The reference teaches that human sera reacted with the peptides consisting of amino acid residues 363-373 of PAc (see Figs. 3-5 and page 4040), or amino acid residues 319-328 of PAc (see Figs. 3 and 4; and, page 4037), and that antibodies in saliva were similar in reactivity to

those found in the serum of the same donor (see Figs. 3 and 4; and, page 4037). Inherently, the rPAc peptides have the sequence(s) as instantly claimed in the A-region therein (amino acid residues 219-464). Inherently, antibodies that bind to a short linear peptide entirely contained within a longer linear peptide, which do not depend upon a terminal amino or carboxyl group for binding, also bind to the longer peptide.

Applicant's arguments filed 18 January 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, recitations of intended use, or of an intended result, or of a characterization of the results of the active measuring step(s) do not result in a manipulative difference as compared to the prior art.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 8 is rejected under 35 U.S.C. § 103 (a) as being unpatentable over Matsushita et al. (Inf. Imm. 62: 4034, 1994).

The teachings of the reference are as set forth in the prior Office action and above and differ from the invention as instantly claimed in teaching an enzyme label rather than a fluorescent label on the anti-immunoglobulin A antibodies.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have substituted any conventional label on the detection antibodies of Matsushita et al. because one would have had obvious motivation and a reasonable expectation that any alternative label would successfully perform the detection function and such substitution is an obvious matter of design choice depending upon signal detection preference.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James L. Grun, Ph.D.
April 9, 2007

LONG V. LE 04/04/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600